



General

Guideline Title

Final recommendation statement: folic acid for the prevention of neural tube defects: preventive medication.

Bibliographic Source(s)

Final recommendation statement: folic acid for the prevention of neural tube defects: preventive medication. [internet]. Rockville (MD): U.S. Preventive Services Task Force (USPSTF); 2017 Jan [7 p]. [33 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force. Folic acid for the prevention of neural tube defects: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2009 May 5;150(9):626-31.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the Levels of Certainty regarding Net Benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendation and Evidence

The USPSTF recommends that all women who are planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400-800 µg) of folic acid (A recommendation).

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to women who are planning or capable of pregnancy (see Figure 2 in the original guideline document). It does not apply to women who have had a previous pregnancy affected by neural tube defects or who are at very high risk due to other factors (e.g., use of certain antiseizure

medications or family history). These women may be advised to take higher doses of folic acid.

Assessment of Risk

Although all women of childbearing age are at risk of having a pregnancy affected by neural tube defects and should take folic acid supplementation, some factors increase their risk, including a personal or family history (first- or second-degree relative) of neural tube defects. Women with a personal history of an affected pregnancy require special care and are not within the scope of this recommendation statement. Other risk factors include the use of particular antiseizure medications (e.g., valproic acid or carbamazepine), maternal diabetes, obesity, and mutations in folate-related enzymes.

Questions persist regarding increased risk of neural tube defects in some racial/ethnic groups. Birth prevalence rates are highest among Hispanic women, followed by non-Hispanic white and non-Hispanic black women. Genetic mutations in folate-related enzymes may vary by race/ethnicity. Dietary folate or folic acid intake differs by race/ethnicity. For example, Mexican American women may be at increased risk because of decreased consumption of fortified foods and greater intake of corn masa-based diets. Fewer Hispanic women (28%) report consuming 0.4 mg (400 µg) or more of folic acid daily through fortified food or supplements, compared with 39% of non-Hispanic white women.

Timing

Half of all pregnancies in the United States are unplanned. Therefore, clinicians should advise all women who are capable of pregnancy to take daily folic acid supplements. The critical period for supplementation starts at least 1 month before conception and continues through the first 2 to 3 months of pregnancy.

Dosage

Trials and observational studies conducted in settings without food fortification suggest that supplementation with a multivitamin containing 0.4 to 0.8 mg (400-800 µg) of folic acid decreases the risk of neural tube defects. Evidence shows that most women in the United States are not consuming fortified foods in a quantity needed to demonstrate optimal benefit. An analysis of National Health and Nutrition Examination Survey (NHANES) data found that 48% of respondents of childbearing age consumed the recommended amount of folic acid from mandatorily fortified foods only.

According to the National Academy of Sciences Food and Nutrition Board, the tolerable upper intake level of folic acid in women 19 years and older is 1 mg/d (1000 µg/d) from supplements or fortified food (excluding naturally occurring folate) and 0.8 mg/d (800 µg/d) for those aged 14 to 18 years. Fewer than 3% of girls and women aged 14 to 50 years receive more than 1 mg/d (1000 µg/d) of folic acid from supplements or food.

Additional Approaches to Prevention

The Community Preventive Services Task Force recommends community-wide education campaigns to encourage women of childbearing age to take folic acid supplements.

In 2016, the U.S. Food and Drug Administration approved folic acid fortification of corn masa flour. This allows manufacturers to voluntarily add folic acid to corn masa flour at levels consistent with those found in other enriched cereal grains.

Definitions

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is	Offer or provide this service.

Grade	Definition	Suggestions for Practice
	moderate or there is moderate certainty that the net benefit is moderate to substantial.	
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> The number, size, or quality of individual studies Inconsistency of findings across individual studies Limited generalizability of findings to routine primary care practice Lack of coherence in the chain of evidence <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> The limited number or size of studies Important flaws in study design or methods Inconsistency of findings across individual studies Gaps in the chain of evidence Findings not generalizable to routine primary care practice A lack of information on important health outcomes <p>More information may allow an estimation of effects on health outcomes.</p>

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Neural tube defects, including spina bifida and anencephaly

Guideline Category

Prevention

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To update the 2009 U.S. Preventive Services Task Force (USPSTF) recommendation on folic acid supplementation in women of childbearing age

Target Population

Women who are planning or capable of pregnancy

Note: This guideline does not apply to women who have had a previous pregnancy affected by neural tube defects or who are at very high risk due to other factors (e.g., use of certain antiseizure medications or family history).

Interventions and Practices Considered

Folic acid supplementation

Major Outcomes Considered

- Key Question 1
 - a. To what extent does folic acid supplementation reduce the risk for neural tube defects (NTDs) (first occurrence) in women of childbearing age?
 - b. Does the effect of folic acid supplementation on NTDs (first occurrence) differ by race or ethnicity?

- c. Do the benefits of folic acid supplementation differ by dosage, timing, or duration of therapy?
- Key Question 2
 - a. Are there harms associated with folic acid supplementation to the mother, fetus, neonate, or child?
 - b. Do the harms of folic acid supplementation differ by dosage, timing, or duration of therapy?

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic review of the literature was prepared by the RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Sources and Searches

The investigators searched PubMed, the Cochrane Library, and EMBASE for English-language articles published from database inception through January 28, 2016. The search strategies for these databases are listed in the eMethods in the systematic review supplement. Unpublished literature was searched for in ClinicalTrials.gov, HSRProj (Health Services Research Projects in Progress), the World Health Organization's International Clinical Trials Registry Platform, and National Institutes of Health (NIH) Reporter. To supplement electronic searches, the reference lists of pertinent articles and all suggested citations from peer reviewers were reviewed. Ongoing surveillance was conducted after January 2016 through article alerts and targeted searches of high-impact journals to identify major studies published in the interim that may affect the conclusions or understanding of the evidence and therefore the related USPSTF recommendation. The last surveillance was conducted on November 11, 2016.

Study Selection

Two investigators independently reviewed titles, abstracts, and full-text articles using prespecified inclusion criteria for each Key Question (KQ) (see eTable 1 in the systematic review supplement).

Studies were included if they focused on the use of folic acid supplementation for the prevention of neural tube defect (NTD)-affected pregnancies in women of childbearing age. Not included were studies of prepubertal girls or men or women without the potential for childbearing (e.g., postmenopausal, genetic, uterine, or ovarian abnormalities). The investigators searched for studies that examined the use of folic acid supplementation with or without food fortification or naturally occurring folate for the prevention of NTDs. They also searched for studies that examined the supplementation of micronutrients (e.g., multivitamin, iron) in combination with folic acid for the prevention of NTDs. For all KQs, they searched for studies conducted in the United States or in countries rated "very high" on the United Nations Human Development Index.

Studies were included that compared interventions with placebo, no treatment, dietary supplementation only, supplementation with prenatal vitamins without folic acid, or iron supplements without folic acid for

questions on benefits and harms and variations in subpopulations (KQs 1a, 1b, and 2a). Included studies compared interventions with lower or higher dose of folic acid supplementation only for questions about variations in benefits and harms by dosage (KQs 1b, 1c, and 2b).

Studies were sought that reported on the benefits of folic acid supplementation initiated before the index pregnancy or in the first trimester to prevent NTDs for questions on benefits and variation in benefits in subpopulations (KQs 1a and 1b). The timing of the intervention was expanded through the end of the pregnancy for questions on the effect of timing on benefits or any harms questions (KQs 1c, 2a, and 2b).

For benefits and harms (KQs 1 and 2), randomized clinical trials (RCTs), nonrandomized controlled trials, cohort studies, case-control studies, and systematic reviews were included. Additionally, for harms (KQs 2a and 2b), registry data were included. Two reviewers dually reviewed the quality of all studies included in the 2009 report that met the inclusion criteria for the current review and resolved disagreement by discussion and consensus.

Number of Source Documents

See the literature search flow diagram (Figure 2) in the evidence report (see the "Availability of Companion Documents" field) for a summary of evidence search and selection.

Articles included for Key Questions:

- Key Question 1a: 20 articles

- Key Question 1b: 3 articles

- Key Question 1c: 8 articles

- Key Question 2a: 20 articles

- Key Question 2b: 6 articles

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Two independent investigators assessed the quality of each study as good, fair, or poor, using predefined criteria developed by the U.S. Preventive Services Task Force USPSTF and adapted for this topic (see eTables 2, 3, 4, and 5 in the systematic review supplement [see the "Availability of Companion Documents" field]).

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic review of the literature was prepared by the RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Extraction and Quality Assessment

For each included study, one investigator extracted information about methods, patient population, intervention, comparator, outcomes, timing, setting, and study design, and a second investigator reviewed for completeness and accuracy. Two independent investigators assessed the quality of each study as good, fair, or poor, using predefined criteria developed by the USPSTF and adapted for this topic (see eTables 2, 3, 4, and 5 in the systematic review supplement).

Disagreements were resolved by discussion and consensus. Issues leading to a judgment of poor quality included the risk of misclassification bias from retrospective recall of level and timing of exposure; the risk of selection bias from not identifying all cases of the outcome, including fetal deaths; and the risk of confounding from not appropriately accounting for factors such as infertility that might influence both exposure to folic acid supplementation and the outcome of twinning. Studies with 1 or more of these features were rated as poor quality. Other flaws that resulted in poor-quality ratings included initially assembled groups not close to being comparable or maintained throughout the study (including overall attrition of at least 20% or differential attrition of at least 15% between groups); use of unreliable or invalid measurement instruments or unequal application among groups (including not masking outcome assessment); and, for randomized controlled trials (RCTs), the lack of intention-to-treat analysis.

Data Synthesis and Analysis

Findings for each Key Question were qualitatively synthesized by summarizing the characteristics and results of included studies in tabular or narrative format. To determine whether meta-analyses were appropriate, the clinical and methodological heterogeneity (in population, interventions, and outcomes) of the studies were assessed following established guidance.

Methods Used to Formulate the Recommendations

- Balance Sheets
- Expert Consensus

Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

U.S. Preventive Services Task Force Recommendation Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

*A, B, C, D, and I (*Insufficient*) represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a

general primary care population. For screening topics, this standard could be met by a large randomized controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

- Do the studies have the appropriate research design to answer the key question(s)?
- To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
- To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
- How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
- How consistent are the results of the studies?
- Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose-response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion

Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med.* 2007;147:871-875. [5 references].

Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<div>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: The number, size, or quality of individual studies Inconsistency of findings across individual studies Limited generalizability of findings to routine primary care practice Lack of coherence in the chain of evidence</div> As more information becomes available, the magnitude or direction of the observed effect

Level of Certainty	Description
	could change, and this change may be large enough to alter the conclusion.
	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:
	<ul style="list-style-type: none"> The limited number or size of studies Important flaws in study design or methods Inconsistency of findings across individual studies Gaps in the chain of evidence Findings not generalizable to routine primary care practice A lack of information on important health outcomes
	More information may allow an estimation of effects on health outcomes.

Cost Analysis

The U.S. Preventive Services Task Force (USPSTF) does not consider the costs of providing a service in this assessment.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review

Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center (EPC) and the Agency for Healthcare Research and Quality (AHRQ) send the draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. The draft evidence review is also posted on the USPSTF Web site for public comment. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF website from May 10 to June 6, 2016. Some comments requested a more detailed definition of "excessive" folic acid. In response, the USPSTF added information about tolerable upper intake levels for folic acid. Other comments suggested emphasizing that many women do not meet daily recommended amounts of folic acid and adding language on the potential harms of folic acid supplementation. The USPSTF added language about the harms of supplementation and the difficulty of consuming enough folic acid from food alone.

Comparison with Guidelines from Other Groups

Recommendations for screening from the following groups were discussed: the Health and Medicine

Division of the National Academies (formerly the Institute of Medicine), the American College of Obstetricians and Gynecologists, American Academy of Family Physicians, the U.S. Public Health Service, the Centers for Disease Control and Prevention, the American Academy of Pediatrics, the American Academy of Neurology, and the American College of Medical Genetics and Genomics.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Benefits of Preventive Medication

The U.S. Preventive Services Task Force (USPSTF) found convincing evidence that folic acid supplementation in the periconceptional period provides substantial benefits in reducing the risk of neural tube defects in the developing fetus. The USPSTF found inadequate evidence on how the benefits of folic acid supplementation may vary by dosage, timing relative to pregnancy, duration of therapy, or race/ethnicity.

Potential Harms

Harms of Preventive Medication

The U.S. Preventive Services Task Force (USPSTF) found adequate evidence that the harms to the mother or infant from folic acid supplementation taken at the usual doses are no greater than small.

Qualifying Statements

Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services.

Implementation of the Guideline

Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its [Web site](#) . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

Implementation Tools

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Jan

Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services or its agencies.

Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality (AHRQ) support the operations of the USPSTF.

Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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*Members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to <https://www.uspreventiveservicestaskforce.org/Page/Name/our-members> .

Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

Disclosures

All authors have completed and submitted the International Committee of Medical Journal Editors (ICMJE) Form for Disclosure of Potential Conflicts of Interest. Authors followed the policy regarding conflicts of interest described at <https://www.uspreventiveservicestaskforce.org/Page/Name/conflict-of-interest-disclosures> . All members of the USPSTF receive travel reimbursement and an honorarium for participating in USPSTF meetings.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force. Folic acid for the prevention of neural tube defects: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2009 May 5;150(9):626-31.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#) .

Availability of Companion Documents

The following are available:

Evidence Reviews:

Viswanathan M, Treiman KA, Doto JK, Middleton JC, Coker-Schwimmer EJJ, Nicholson WK. Folic acid

supplementation for the prevention of neural tube defects: an updated evidence report and systematic review for the U.S. Preventive Services Task Force. JAMA. 2017 Jan 10;317(2):183-9. Viswanathan M, Treiman KA, Doto JK, Middleton JC, Coker-Schwimmer EJJ, Nicholson WK. Folic acid supplementation: an evidence review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 145. AHRQ Publication No. 14-05214-EF-1. Rockville (MD): Agency for Healthcare Research and Quality; 2017 Jan. 183 p.

Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#) .

Background Articles:

Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med. 2007;147:123-7.

Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med. 2007;147:117-22.

Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-5.

Available from the [USPSTF Web site](#) .

The following are also available:

Folic acid for the prevention of neural tube defects: preventive medicine. Clinical summary. Rockville (MD): U.S. Preventive Services Task Force; 2017 Jan. 1 p. Available from the [USPSTF Web site](#) .

The [Electronic Preventive Services Selector \(ePSS\)](#) is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

Patient Resources

The following is available:

Folic acid supplementation for prevention of neural tube defects. JAMA patient page. JAMA. 2017 Jan 10;317(2):222.

Myhealthfinder is a tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the U.S. Preventive Services Task Force (USPSTF) and is available at [www.healthfinder.gov](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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